CAO MANAGEMENT PROCEDURE
Carlsbad Area Office

MP No. 10.3 Page 1 of 33

Revision 3

Title: **AUDITS**

Manager, Carlsbad Area Office — Effective Date: 11/24/99

1.0 PURPOSE

The purpose of this procedure is to define the process, responsibilities and controls for the planning and conduct of independent announced and unannounced audits by the Carlsbad Area Office (CAO) of activities that relate to regulatory compliance, quality, safety, certification, or waste isolation.

2.0 SCOPE

This procedure specifies the methods for the scheduling, selection of personnel, planning, performing, reporting, and closure of independent CAO audits, both internal and external, performed by or for the CAO. This procedure does not apply to internal management or self-assessments. It is not applicable to administrative audits, e.g., financial, accounting, personnel, etc. Audits of sites may be either announced or unannounced. This procedure supersedes MP 10.3, Revision 2, Audits.

3.0 REFERENCES AND DEFINITIONS

3.1 References

3.1.1 DOE CAO Quality Assurance Program Document (QAPD) CAO-94-1012

3.1.2 CAO Management Procedure (MP) 3.1, *Corrective Action Reports*

3.1.3 CAO Team Procedure (TP) 3.2, *Corrective Action Report (CAR) Trend Analysis and Reporting*

3.1.4 CAO MP 4.9, *Quality Assurance Records*

3.1.5 CAO TP 10.1, *Qualification of Personnel and Certification of Lead Auditors*

3.1.6 WIPP Hazardous Waste Facility Permit

3.2 Definitions

3.2.1 Adequacy - Addresses the flow-down or incorporation of requirements from upper tier program documents (e.g., CAO QAPD) into implementing procedures.

3.2.2 Assessment - Generic term for an evaluation of work done. Assessments include audits, surveillances, management assessments, and reviews.

3.2.3 Assessment Team Leader - The person selected to lead an assessment. For audits the person shall be qualified and certified in accordance with TP 10.1.

3.2.4 Audit - A planned and documented independent evaluation of quality assurance and/or technical program, performed to determine by investigation of objective evidence the adequacy of, and compliance with, established quality assurance and/or technical implementation procedures, and the effectiveness of implementation of these procedures.

3.2.5 Auditor - An individual who is qualified to perform assigned portions of an audit.

3.2.6 Audit Team - An audit team consists of an audit team leader and may include one or more auditors or technical specialists who have been assigned to participate in an audit.

3.2.7 Audit Team Leader - An individual who is independent, qualified, and certified as a lead auditor in accordance with TP 10.1 and has been selected to lead an audit.

3.2.8 Condition Adverse to Quality - An all-inclusive term used in reference to failures, malfunctions, deficiencies, discrepancies, defective items, nonconformances, and technical inadequacies.

3.2.9 Corrective Action Report (CAR) - A document used to identify and document conditions adverse to quality, as well as actions taken to correct and, if required, to preclude recurrence of those conditions.

3.7.10 Deficiency - Any failure to comply with an applicable requirement.

3.2.11 Effectiveness - A determination of whether the controls established in the implementing procedure produce the desired results or end product.

3.2.12 External Audit - An audit conducted by or for the CAO of an organization performing work under the direction of CAO, but not in the CAO's organizational structure.

3.2.13 Implementation - Determines the extent of compliance with procedures.

3.2.14 Independent Assessment - An assessment that is conducted by an independent group or organization, having authority and freedom from the audited organization, to evaluate the scope, status, adequacy, programmatic compliance, or effectiveness of a program or activity.

3.2.15 Internal Audit - An audit conducted by or for the CAO of an organization within the CAO's organizational structure.

3.2.16 Lead Auditor - An individual trained, qualified, and certified in accordance with the requirements of TP 10.1.

3.2.17 Objective Evidence - Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item, service, process, or end-product and based upon direct observation, measurement, test, or documentation that can be verified.

3.2.18 Observer - An individual who observes the audit process, but does not directly participate in the audit.

3.2.19 Observation - Documentation of marginally acceptable conditions that, if not controlled, might later escalate into a deficiency. Observations are not deficiencies and do not require a response.

3.2.20 Recommendation - Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing process or quality program requirements.

3.2.21 Technical Specialist - An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the adequacy, implementation, and effectiveness of the technical processes and activities.

3.2.22 WAP (Waste Analysis Plan) Related – An audit activity performed for purposes of compliance with the audit requirements contained in the WIPP Hazardous Waste Facility Permit.

4.0 RESPONSIBILITIES

4.1 Manager, Carlsbad Area Office

The CAO Manager is responsible for approving the CAO assessment schedule.

4.2 Assistant Managers

The assistant managers are responsible for ensuring the development, implementation and maintenance of effective assessment programs within their areas of responsibility. Specific responsibilities include:

4.2.1 Review proposed assessment schedules with team leaders within their organization.

4.2.2 Upon request of the CAO Quality Assurance (QA) Manager recommend and provide staff members to perform as observers, technical specialists, or auditors.

4.3 CAO Team Leaders

CAO team leaders are responsible for coordinating with the CAO QA Manager the planning and scheduling of internal audits within their areas of responsibility and for facilitating the

conduct of internal audits. CAO team leaders also have the following responsibilities with respect to the planning and conduct of independent external audits within their area of responsibility (exclusive of those external audits which may be chartered by the CAO QA Manager when exercising responsibility as the CAO's independent assessment function).

4.3.1 Coordinate the scheduling and conduct of external audits with their assistant managers and the CAO QA Manager.

4.3.2 Coordinate with the CAO QA Manager in providing auditor resources.

4.3.3 When CAO personnel are used, selection of the audit team leader and concurring with the selection of the audit team personnel.

4.3.4 Issuance of the audit plan and audit notification letter.

4.3.5 Coordinate personnel interfaces and access, as required, for audit performance.

4.3.6 Issuance of the audit report.

4.3.7 Processing CAR's in accordance with MP 3.1.

4.3.8 Completion of QA records created through this procedure in accordance with MP 4.9.

4.4 CAO QA Manager

The CAO QA Manager is responsible for:

4.4.1 Maintaining the overall CAO independent assessment program.

4.4.2 Coordinating with CAO assistant managers and team leaders to include audits in the CAO assessment schedule.

4.4.3 Conducting assessments of the CAO QA Program, independent of line management. This includes the scheduling of internal audits as necessary to fulfill the responsibilities of the CAO independent assessment function.

4.4.4 Issuing the audit report.

4.4.5 Processing and maintaining QA records created through this procedure in accordance with MP 4.9.

4.5 Audit Team Leader

The audit team leader is responsible for:

4.5.1 Preparing the audit plan and notification letter.

4.5.2 Selecting personnel for the audit team and verifying that audit team members are properly qualified, trained, and are independent of the activity being audited.

4.5.3 Coordinating with audit observers.

4.5.4 Approving the audit checklist.

4.5.5 Conducting the pre- and postaudit conferences.

4.5.6 Coordinating the conduct of the audit.

4.5.7 Coordinating the resolution of emergent issues and providing guidance to the audit team as necessary during the conduct of the audit.

4.5.8 Determining and reporting the adequacy, implementation, and effectiveness of the processes audited, in accordance with the audit scope.

4.5.9 Preparing the audit report and any CAR's.

4.5.10 Collecting and packaging audit records.

NOTE: When the audit team leader is a contractor, preliminary draft documents will be provided to the CAO for finalization and issuance. Personnel to conduct the audit will be selected by the contractor. Coordination with regulators will be conducted through the CAO QA Manager.

4.6 Audit Team

The audit team is responsible for:

4.6.1 Preparing audit checklists.

4.6.2 Attending audit-related meetings.

4.6.3 Conducting assigned portions of the audit.

4.6.4 Assisting in the preparation of the audit report and any CAR's.

5.0 PROCEDURE

5.1 Scheduling

5.1.1 Quarterly, the CAO QA Manager will prepare a combined assessment schedule (attachment I) that lists all assessment activities for the CAO. These activities shall include:

a. Internal and External Audits
b. Internal and External Surveillances
c. Management Assessments

5.1.2 Audits shall be scheduled to begin as early in the life of a project or activity as practicable and continue at intervals consistent with the schedule for accomplishing the work and commensurate with the assigned control level. Site Waste Analysis Plan (WAP)-related audits shall be performed at least annually. The following should be considered when scheduling:

a. Work activities, level of effort, risk, and importance to regulatory compliance, safety, TRU waste site certification, or waste isolation issues.

b. A review of documentation furnished by, or regarding the work of, the organization or supplier (such as certificates of conformance, nonconformance notices, and corrective actions).

c. Consideration of previous assessment results, trends, corrective actions, effectiveness, and ancillary information (e.g., information from other sources such as industry or other DOE organizations, regulating bodies, etc.).

d. A review of previous assessments from identical or similar products or services furnished by the same organization or supplier.

e. Results of surveillance activities.

5.1.3 Scheduled audits shall be supplemented, as necessary, to provide continuing coverage of work activities that relate to regulatory compliance, safety, TRU waste site certification, or waste isolation for any of the following reasons:

a. Determine the adequacy, implementation, and effectiveness of DOE contractor activities after contract award.

b. When significant changes have been made to a program, or if significant organizational changes have been made.

c. When declining trends in quality performance have been observed or are suspected.

d. When it is necessary to verify implementation of extensive, large-scale corrective action activities.

5.1.4 The CAO Manager shall approve the quarterly assessment schedule for issue by the CAO QA Manager.

5.1.5 Monthly updates will be prepared by the CAO QA Manager, but will not be signed by the CAO Manager. Copies of the quarterly assessment schedules and the monthly updates will be forwarded to the New Mexico Environmental Department (NMED). Transmittal of these schedules will constitute the 30 calendar day notice to NMED prior to each audit.

5.2 Personnel Selection

5.2.1 The audit team leader shall be selected by the responsible team leader from a list of lead auditors for independent external audits, and by the CAO QA Manager for internal audits and external QA organizational audits. Audit team members shall be selected by the audit team leader, subject to the concurrence of the responsible team leader, as applicable.

5.2.2 The members of the audit team shall be selected based on independence from the organization or activities being audited and assurance that they have sufficient authority and organizational freedom to objectively identify problems.

5.2.3 The audit team leader shall:

a. Review the training and qualifications of prospective audit team personnel and concur that they have the collective experience and training commensurate with the scope, complexity, or special nature of the activities to be audited. For WAP related audits, the auditors/technical specialists shall have expertise in the Resource Conservation and Recovery Act (RCRA) requirements and knowledge of the analysis and documentation methods required to verify the hazardous waste characterization performed by the sites. For WAP related audits of acceptable knowledge, the auditors/technical specialists shall understand the required acceptable knowledge information, RCRA regulations, and EPA guidance regarding the use of acceptable knowledge for waste characterization, RCRA hazardous waste characterization, and the WAP. Audit team members will be independent of all TRU mixed waste management operations at the site being audited. The auditors/technical specialists shall have expertise in the specific audit areas to which they are assigned.

b. Use technical specialists, as applicable, when assessing the effectiveness of technical processes and the acceptability of technical end-products.

5.2.4 For WAP related audits, the CAO QA Manager shall identify all audit team members to the NMED prior to the audit and shall provide the qualifications of all audit team members upon request.

5.3 Planning

NOTE: When the audit team leader or auditor is a contractor, preliminary draft documents will be provided to the CAO for finalization and issuance. Coordination with regulators will be conducted through the CAO QA Manager.

5.3.1 The audit team leader shall develop an audit plan similar to attachment II that identifies the following:

a. Scope, schedule, and the procedures or checklists to be used.

b. Names of the audit team leader, the audit team members, and observers.

c. Applicable requirements documents.

d. Activities/contracts/tasks to be audited.

e. Corrective action follow-up for previous audit(s) shall be included in the scope, if applicable.

f. Organizations to be notified.

5.3.2 The audit team leader shall prepare an audit notification letter addressed to the key individual of the organization to be audited. It shall include:

a. The name of the audit team leader.

b. The audit plan, as an attachment.

c. When applicable, a request for documents for prior review, access clearances, or other action items necessary to facilitate the audit.

5.3.3 The audit plan, along with the audit notification letter, shall be forwarded to the CAO QA Manager for review and concurrence. The audit notification letter should arrive at the organization to be audited at least ten (10) working days prior to the scheduled audit. For WAP related audits, the audit plan shall be provided to NMED prior to the audit.

5.3.4 The audit team leader shall prepare the audit team for the audit using an orientation which shall include the following items as appropriate:

a. Audit objectives and the audit scope.

b. Procedures and other documents that apply to the activities being audited.

c. Previous assessment results and completed or in-process corrective actions.

d. New programs or activities being audited .

e. Changes in programs or operations .

f. Changes in key personnel .

g. Current status of the work .

h. Role of the auditors in conducting the audit .

i. Role of the observers.

5.3.5 The audit team shall develop audit checklists using a format similar to attachment III. Checklists shall be based upon applicable quality assurance and technical procedures and regulatory and contractual requirements, as specified in the audit plan. The checklists shall be reviewed and approved by the audit team leader to assure complete coverage of assigned scope and should be forwarded to the audited organization before the start of the preaudit meeting. The audit checklists for WAP related audits shall be forwarded to NMED prior to the preaudit meeting. The audit checklists shall be used by the audit team to:

a. Guide the audit.

b. Record objective evidence (e.g., activities, procedures, instructions, items, records, and personnel interviewed). Optional forms attachment VII, Personnel Contacted During the Audit, and attachment VIII, Objective Evidence Reviewed may be used to record information.

c. Review corrective actions taken since the last audit.

d. Document adequate and inadequate conditions and implementation for each checklist item.

5.3.5.1 For WAP related audits, the checklists shall include, at a minimum, the appropriate checklists found in Permit Tables B6-1 through B6-6 for the summary category group undergoing audit.

5.3.5.2 For WAP related AK audits, the checklist shall include Table B6-3 of the permit, and will include but not be limited to the following elements for review during the audit:

a. Documentation of the process used to compile, evaluate, and record acceptable knowledge is available and implemented

b. Personnel qualifications and training are documented

c. All of the required acceptable knowledge documentation specified in section B4-2 of the permit has been compiled in an auditable record

d. All of the required procedures specified in section B4-3 of the permit have been developed and implemented, including but not limited to

1. A procedure exists for assigning hazardous waste codes to waste streams in accordance with section B4-3 of the permit

2. A procedure exists for resolving discrepancies in acceptable knowledge documentation in accordance with section B4-3 of the permit

3. A procedure exists for confirming acceptable knowledge information through: a) radiography or visual examination, b) headspace gas sampling and analysis, and c) homogeneous waste sampling and analysis in accordance with section B4-3 of the permit

e. Results of other audits of the TRU mixed waste characterization programs at the site are available in site records.

5.4 Performance

5.4.1 The audit team leader shall conduct a preaudit conference with the appropriate personnel within the audited organization. Meeting attendance will be documented, using an attendance record similar to attachment IV. The purpose of this meeting is to:

a. Introduce the audit team, participants, and observers.

b. Obtain additional information on the organization and status of work being done.

c. Discuss the audit objectives, scope, and conduct.

d. Identify the specific areas to be audited.

e. Identify the processes or functions to be observed.

f. Provide information on the audit activities and schedule.

g. Arrange for contacts and escorts, when needed.

h. Discuss logistics and meeting schedules.

i. Arrange for site participation required, including site interfaces.

5.4.2 Audits shall include site personnel interviews, document and record reviews, observations of operations, and any other activities deemed necessary by the auditors to meet the objectives of the audit. Observations or deficiencies identified during the audit will be investigated or evaluated, as necessary, to determine if they are isolated conditions or represent a general breakdown of the waste characterization quality assurance program. During audit interviews or audit meetings, site personnel may be advised of deficiencies identified within their areas of responsibility to establish a clear understanding of the identified condition.

5.4.3 The site personnel will be given the opportunity to correct any deficiency that can be corrected during the audit period. Deficiencies and observations will be documented and included as part of the audit report. Those items that have been resolved during the audit (isolated deficiencies that do not require a root cause determination or actions to preclude recurrence) will be verified prior to the end of the audit, and the resolution will be described in the audit report. Those items that affect the quality of the program, and/or the data generated by that program, which are required by the WAP will be documented on a CAR and included as a part of the final audit report. For WAP related audits, RCRA-related CAR's identified by the site during self-audits will be evaluated during the audit.

5.4.4 Audit team members may conduct inspection tours of waste generating stations, analytical laboratories, calibration facilities, and administrative and document control/record facilities,

5.4.5 Objective evidence shall be examined to the detail necessary to determine whether quality assurance and technical program requirements are adequately documented, are being implemented, and the associated work processes are effective.

5.4.6 Technical specialists shall review processes, records, and other associated documentation to determine that the work has been performed in accordance with approved procedures, that the procedures are technically adequate, and that the activities and results are properly documented, defensible, and effective.

5.4.7 Audit team members shall complete their assigned portions of the checklist. Results of the examination shall be noted on the checklist as satisfactory, unsatisfactory, not applicable, or indeterminate. Any applicable CAR's, observations, and recommendations shall be noted in the Aresults" column. The identification of documentation that supports the notation shall be recorded in the Aobjective evidence" column of the checklist, where applicable. Sample size and results shall be identified on the checklist. The reason for designating "not applicable" or Aindeterminate" shall also be recorded.

5.4.7.1 For WAP related audits the B6 checklist must indicate that the objective evidence observed verifies that the site has met the QAOs for the program elements, methods, and the activities being audited.

5.4.7.2 In cases where discrepancies exist between the audit checklists and requirements documents, the requirements documents take precedence. Auditors shall add items and make corrections to the checklist during the course of the audit as necessary to meet the audit scope. Changes will be clearly designated on the checklists.

5.4.8 Conditions adverse to quality that, in the auditor's judgment, require prompt corrective action, shall be reported immediately to the management of the audited organization and documented on the checklist.

5.4.9 Conditions adverse to quality shall be documented on a CAR or on attachment X, (CDA). The audit team member who identifies each deficiency must participate in the preparation of the CAR or CDA to the extent necessary to identify relevant issues. CAR's associated with the audit shall be prepared in accordance with MP 3.1, *Corrective Action Reports,* and shall be supported by objective evidence recorded on the checklists. Sample sizes and specific examples shall also be recorded to substantiate deficient conditions.

5.4.10 Observations, as explained in the definition, shall be recorded on the checklist.

5.4.11 Exemplary performance observed during the audit shall be identified, documented, and reported.

5.4.12 Suggestions that are directed toward identifying opportunities for improvement, enhancing the methods of implementing quality program requirements, or achieving technical objectives shall be identified as recommendations.

5.4.13 When considered necessary by the audit team leader, the audit team leader shall conduct daily team caucuses to gather details of the audit results as they occur and to summarize the audit results in preparation for the daily meetings with the management of the audited organization. The Audit Concern Form, attachment IX, may be used to document items for the team caucus.

5.4.14 When considered necessary by the audit team leader, the audit team leader shall conduct daily meetings with the management of the audited organization during the course of the audit to provide feedback relative to audit concerns, results, and progress.

5.4.15 The audit team leader should consult with the responsible team leader on any issues discovered during the audit prior to the postaudit conference.

5.4.16 The audit team leader shall conduct a postaudit conference with the management of the audited organization. Meeting attendance shall be documented using an attendance record similar to attachment IV. The postaudit conference discussion shall include the following:

a. Audit results, including deficiencies that will be documented on CAR's, and those corrected during the audit.

b. Any observations.

c. Any improvement recommendations.

d. Any positive reinforcement of exemplary practices.

e. Probable schedule for issuance of the audit report and any CAR's.

f. Any feedback from the audited organization and observers regarding the conduct of the audit.

g. A statement of the overall adequacy, implementation, and effectiveness of the audited processes within the scope of the audit.

5.5 Reporting

NOTES:

1) When the audit team leader or auditor is a contractor, preliminary draft documents will be provided to the CAO for finalization and issuance.

2) Separate audit reports for WAP-related and non-WAP-related portions of the same audit may be prepared at the CAO QA Manager's option.

5.5.1 An audit report (see attachment V) shall be prepared and signed by the audit team leader, then sent to the CAO QA Manager for review and approval. The audit report shall contain the following information:

a. An executive summary of the audit results, including a brief overview of the audit scope, any conditions adverse to quality, a listing of observations, recommendations, any exemplary practices, and a statement of the overall effectiveness of the area(s) and activities audited.

b. Audit number, date of the audit, and organization audited.

c. Identification of the audit team leader, auditors, observers, and any technical specialists.

d. Identification of the personnel attending the preaudit conference, those contacted during the audit, and those attending the postaudit conference.

e. Summary of documents reviewed and pertinent results. An audit summary table similar to attachment VI may be used to summarize audit activities and results.

f. Pertinent details of any technical evaluations that were performed.

g. Details of any conditions adverse to quality and the associated CAR's, a description of the resolution of any items corrected during the audit, any observations, and any recommendations.

h. Audit findings of a common nature shall be grouped in the report whenever possible so that related or systematic breakdowns in the QA program are identified. Deficiencies shall be categorized, based on their relative importance, to indicate their degree of impact on regulatory compliance, safety, TRU waste site certification, or waste isolation.

5.5.2 The audit report shall be reviewed, approved, and issued by the CAO QA Manager. Audit reports shall be issued within 30 days of the completion of the audit. The report distribution shall include: the CAO Manager, the appropriate management of the audited organization, and the responsible assistant manager/ team leader(s). WAP related audit reports will be transmitted to NMED in accordance with the requirements of Section 6.2 and 6.3 of this procedure.

5.6 Audit Response, Follow-up, and Close Out

5.6.1 The audit is considered to be closed upon issuance of the audit report.

5.6.2 Response, follow-up, verification, and closure of CAR's issued during the audit shall be in accordance with the requirements of MP 3.1.

6.0 RECORDS

6.1 The following documentation generated as a result of implementing this procedure shall be processed when the audit report is issued and maintained as QA records in accordance with MP 4.9, Quality Assurance Records.

a. Audit Plan

b. Audit Notification Letter

c. Audit Report

d. Audit Checklists (completed)

e. Annual Evaluations/Assessments

6.2 For WAP related audits, the CAO Certification Manager will forward a copy of these to NMED and the site managing and operating contractor for retention in the operating record until closure.

6.3 For WAP related audits, a "final audit report " shall be prepared. The report shall contain information related to WAP implementation for transmittal to the NMED. This shall include:

a. The WAP related portions of the audit report

b. Completed B.6 checklists

c. WAP related audited procedures

d. Documentation from all associated WAP related CAR's including the CAR, description of all corrective actions taken, and actions taken to close out the CAR

e. Documentation supporting all corrective actions taken on WAP related CAR's

f. Other applicable documents that provide evidence of WAP implementation

7.0 ATTACHMENTS

7.1 Attachment I Assessment Schedule Format

7.2 Attachment II Audit Plan Format

7.3 Attachment III Audit Checklist Format

7.4 Attachment IV Meeting Attendance Record Format

7.5 Attachment V Audit Report Format

7.6 Attachment VI Audit Summary Table Format

7.7 Attachment VII Personnel Contacted During the Audit

7.8 Attachment VIII Objective Evidence Reviewed

7.9 Attachment IX Audit Concern Form

7.10 Attachment XI Corrected During the Audit (CDA) Form

7.11 Attachment XI Procedure Flow Chart

ATTACHMENT I

CAO ASSESSMENT SCHEDULE FORMAT
CARLSBAD AREA OFFICE
ASSESSMENT SCHEDULE
(Example)

APPROVED BY: _____ _____
CAO MANAGER **DATE**

ORGANIZATION/SCOPE	CAO TEAM	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	REMARKS & SCHEDULE

" = PLANNED
! = PERFORMED

ATTACHMENT II
Page 1 of 1

CAO AUDIT PLAN FORMAT
(Example)

Audit Number: _____

Organization: _____ _____

Date and Location of Audit: _____

Audit Team:

Name	Role	Company

Audit Scope:

_____

_____

Governing Documents/Requirements/Criteria to audit and checklist identification:

_____

_____

_____

Activities/Contracts/Tasks to be audited:

_____

_____

_____

Schedule of Audit Activities:

A preaudit conference is scheduled for (date, time, and location)

The audit team caucus will be held (time, days)

The audit team will brief appropriate management (time, days)

A postaudit conference is scheduled for (date, time, and location)

Prepared By:
_____ Audit Team Leader _____ Date _____

Concurrence:
_____ CAO QA Manager _____ Date _____

ATTACHMENT III
Page 1 of 2

CAO AUDIT CHECKLIST FORMAT
(Example)
CAO AUDIT CHECKLIST

Organization Evaluated: _____ Audit Number: _____
Activities Evaluated: _____ Date of Evaluation: _____
Controlling Document(s): _____
_____

Item No.	Requirement(s) and/or Characteristic(s)	Objective Evidence	*Results

Prepared by: _____ Approved by: _____ Page ___ of ___

*Indicate Results: Satisfactory (SAT), Unsatisfactory (UNSAT), Not Applicable (NA), Indeterminate (I)

ATTACHMENT III
Page 2 of 2

CAO AUDIT CHECKLIST FORMAT
(Continuation Sheet)
(Example)

Organization Evaluated: _____ Audit Number: _____
Activities Evaluated: _____

Item No.	Characteristic(s)	Objective Evidence	*Results

Page ____ of ____

ATTACHMENT IV
Page 1 of 1

ATTENDANCE RECORD
(Example)

ATTENDANCE SHEET

Audit Number:_____ Meeting: Preaudit ☐

Date: _____ Time: _____ Postaudit ☐

Other ☐

Print Name	Title	Organization	Phone Number

ATTACHMENT V
Page 1 of 5

U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF

(AUDITED ORGANIZATION)

(ORGANIZATION LOCATION)

AUDIT NUMBER A-YY-XX

(DATE OF THE AUDIT)

(PRIMARY ACTIVITY EVALUATED)

Prepared By: _____ _____
Audit Team Leader **Date**

Approved: _____ _____
CAO QA Manager **Date**

1.0 EXECUTIVE SUMMARY

Audit A-YY-XX was conducted to evaluate the (*adequacy, implementation, and/or effectiveness*) of (*describe the primary activity evaluated*). The audit was conducted at (*location*) from (*dates).* The audit team concluded that (*provide statements on adequacy, implementation and/or effectiveness*). The audit team identified (*number*) conditions adverse to quality resulting in the issuance of (*number of*) Corrective Action Report(s) (CAR's) that require corrective action in the areas of (*identify deficient audited areas*). (*Number of*) isolated deficiencies requiring only remedial actions were corrected during the audit (CDA's). (*Number of*) observations and (number of) recommendations are being offered for management consideration. CAR's, CDA's, Observations, Recommendations, and Exemplary Practices are described in Section 6.0.

2.0 SCOPE

The scope of this (*internal/external*) Audit A-YY-XX, conducted at (*the location of the audit*), was to evaluate the adequacy, implementation, and/or effectiveness of (*describe the subject/activities evaluated*). The following elements were evaluated in accordance with the CAO QAPD (*list the appropriate elements*). The following CAO technical characterization elements were evaluated in accordance with the WAP (*list the appropriate elements*). The following transportation technical elements were evaluated in accordance with the CAO TRAMPAC (*list the appropriate elements*). Evaluation of the (*describe the primary activity evaluated*) was based on current revisions of the following documents (*generally state the basis of the audit*).

3.0 AUDIT TEAM AND OBSERVERS

The audit team consisted of the following personnel: (*List name, title and organization*.)
The following inspectors were present during the audit: (*List name, title, and organization.*)
The following observers were present during the audit: (*List name, title and organization.*)

4.0 AUDIT PARTICIPANTS

The following individuals were involved in the audit: (*List name, title and organization*. *If a substantial number of personnel are contacted, a table may be developed as an attachment to the audit report*).

5.0 AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team concluded that (*provide statements on the adequacy, implementation, and effectiveness of the QA program*).

5.2 QA Program Audit Activities

Details of audit activities, including specific objective evidence reviewed, are contained within the audit checklists. the checklists are maintained as QA records. The quality assurance program procedures evaluated during this audit are provided in Attachment (*number*).

5.3 Technical Activities

Describe the results of the audit in concise terms. Sufficient detail must be provided for technical activities to demonstrate that the technical processes used and the objective evidence reviewed, supports the effectiveness determination. If information is extensive, consider the use of attachments for audit details and identification of the objective evidence reviewed.

6.0 CAR'S, CDA's, OBSERVATIONS, RECOMMENDATIONS, AND EXEMPLARY PRACTICE

6.1 CAR's

6.1.1 CAR's From Previous Audits

The following CAR's were reviewed to ensure the corrective actions were complete and continued to be effectively implemented: (*discuss each CAR evaluated*).

6.1.1 CAR's Initiated as a Result of CAO Audit (*number*)

The following (*number*) CAR's, initiated as a result of Audit (*number*), have been transmitted to (*organization audited*) under separate cover. A brief description of each CAR is provided below. (*Provide summary details of any CAR's.*)

6.2 Deficiencies Corrected During the Audit (CDA)

During the audit, (*organization audited*) was able to correct (*number*) isolated conditions adverse to quality identified in the (*areas audited*). A description of these items and their resolution is given below: *Briefly describe the CDA's and their resolutions.*

6.3 Observations

The following (*number*) Observation were identified during the audit. *Briefly describe the Observations.*

6.4 Recommendations

The following (number) Recommendations are presented for (audited site) management consideration. briefly describe the Recommendations.

6.5 Exemplary Practice

Briefly state any Exemplary Practices observed by the audit team.

7.0 ATTACHMENTS

List the Attachments. Normal attachments are: 1) Personnel Contacted During the Audit and 2) Table of Procedures Audited.

ATTACHMENT V
Page 4 of 5

PERSONNEL CONTACTED				
NAME	**ORG/TITLE**	**PREAUDIT MEETING**	**CONTACTED DURING AUDIT**	**POST AUDIT MEETING**

ATTACHMENT V
Page 5 of 5

PROCEDURES AUDITED

NUMBER	PROCEDURE NUMBER	TITLE
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
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21.		
22.		
23.		
24.		
25.		
26.		
27.		
28.		
29.		

ATTACHMENT VI
Page 1 of 3

AUDIT SUMMARY TABLE FORMAT
(Example)

(1) Program Element	(2) Audited Activity	(4) CAR	(5) CDA	(6) Obs	(7) Rec	(8) Adq	(9) Imp	(10) Eff
	TOTAL							

Legend:
CAR=Corrective Action Report Issued CDA=Corrected During the Audit Obs=Observation Rec=Recommendation Offered
Imp=Implementation Eff=Effectiveness Statement NA=Not Applicable S=Satisfactory
U=Unsatisfactory E=Effective NE=Not Effective Shaded=None
Adq-Adequacy Statement IND=Indeterminate

COMPLETION INSTRUCTIONS FOR THE AUDIT SUMMARY TABLE

The audit summary table is used to identify the details and overall status of the audit results. Completion of the audit summary table provides a summary of the quality and technical activities reviewed by audit checklists and the level of program procedure compliance and effectiveness. The following instructions provide guidance on what information is required for completing each column of the audit summary table:

First Column (Optional)

"Program Element," the program area or criteria (e.g., organization, design control, procurement document) being evaluate should be identified in this column. Generally these are arranged in NQA-1 or QAPD element sequence. Complete this column for each area or criteria being examined.

Second Column

"Audited Activity," description of activity being audited.

Third Column

"CAR,@ the identification number of any CAR(s) related in this Aaudited activity," if any, are identified in this column.

Fourth Column

"CDA," any deficiency or deficiencies identified during the audit of a specific area in which the deficiency or deficiencies were corrected and verified during the audit, should be identified in this column. The entry should correlate with the CDA number in Section 6 of the audit report.

Fifth Column

"Observation," any observation(s) noted during the audit of a specific area, should be identified in this column. The entry should correlate with the observation number in section 6 of the audit report.

Sixth Column

"Recommendation," any recommendation(s) offered during the audit which address a specific activity or area, should be identified in this column. The entry should correlate with the recommendation number in Section 6 of the audit report.

ATTACHMENT VI
Page 3 of 3

COMPLETION INSTRUCTIONS FOR THE AUDIT SUMMARY TABLE (Continued)

Seventh Column

"Adequate," the adequacy of the procedure being evaluated for a specific activity or area, should be identified in this column. A procedure is either Aadequate" (contains all the applicable requirements) "marginally adequate" or is "inadequate"

Eighth Column

"Implementation," the status of implementation of the program document for the specific activity or area being evaluated, should be identified in this column. Implementation is either "satisfactory," "marginally satisfactory," or "unsatisfactory."

Ninth Column

"Effectiveness," the effectiveness of the process described in the procedure being evaluated relative to the achievement of desired results or end product, should be identified in this column. Effectiveness is either "effective," "marginally effective," or "not effective."

The last row of the Table

Summarize columns 3 through 10. Note the total number of CAR's, CDA's, Obs, Rec, are entered into the appropriate column in the "total" row. Under the Adq, Imp, and Eff columns, enter the overall results of the audit.

Note: The table may be altered, depending upon the scope of the audit. For example, if effectiveness is not part of the audit scope, that column is eliminated.

ATTACHMENT VII
Page 1 of 1

Auditor _____ Page___ of___

AUDIT A-XX-XX
PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization and Department	Title	Evaluation Area

ATTACHMENT VIII

AUDIT A-99-24
OBJECTIVE EVIDENCE REVIEWED

	Document No.	Title	Rev	Date

Audit Number: A-99-24 **Date: _____**

AUDIT CONCERN FORM

AUDITOR: _____ **Checklist Activity (Item No): _____**

CONCERN NO. _____

I WHAT IS THE CONCERN:

CONCERN DISCUSSED WITH WHOM: _____
Sample size **Population Size** (If known) _____

II DOCUMENT REQUIREMENTS (Name, Revision, Paragraph):

III CONCERN DISPOSITION:

CDA _____ **REC _____**

CAR _____ **Exemp ____**

OBS _____ **NONE _____**

IV VERIFICATION OF ACTIONS TAKEN DURING THE AUDIT:

V COMMENTS:

Attachment X
Page 1 of 1

CORRECTED DURING THE AUDIT

1.0 CDA #	2.0 Audit Number	3.0 Affected Organization	4.0 Identified By
5.0 Description of Deficiency:			
6.0 Affected Documents:			
7.0 Actions Taken By Auditee:			
Verified By: _____ _____ Auditor Date			Trend Cause Code

* Note: 1) All blocks are to be filled out by the audit team member who identified the deficiency.
2) Trend Cause Codes are provided in Attachment II of TP 3.2.

ATTACHMENT XI
Page 1 of 1

AUDIT PROCESS